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Tau-fluvalinate Summary Document
Registration Review: Initial Docket
December 2010

Registration Review Document for Tau-fluvalinate

Case No. 2295

Approved By:

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12-15-2010
Date

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Please Note

This document summarizes the Environmental Protection Agency's current position on tau-fluvalinate based on the following documents:

1. Registration Review: Preliminary Problem Formulation for Environmental Fate, Ecological Risk, and Endangered Species Assessments for Tau-fluvalinate. December 15, 2010.

2. Tau-fluvalinate. Human Health Assessment Scoping Document in Support of Registration Review. November 8, 2010.

3. Tau-fluvalinate Reregistration Eligibility Decision. September 2005. (Available from http://www.epa.gov/oppsrrd1/REDs/taufluvalinate_red.pdf)

4. Updated Review of Tau-fluvalinate Incident Reports. August 19, 2010.

5. Screening Level Use Analysis (SLUA) for Tau-fluvalinate. January 21, 2010.

6. Appendix A for Tau-fluvalinate. January 13, 2010.

Additional supporting documents for tau-fluvalinate may be found in the docket located on the internet at www.regulations.gov.

I. Preliminary Work Plan – Tau-fluvalinate

Introduction:

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides sold or distributed in the United States (U.S.) generally must be registered by the Environmental Protection Agency (EPA or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of tau-fluvalinate.

Tau-fluvalinate is a broad-spectrum insecticide/miticide in the pyrethroid class of pesticides. It is registered for a single food use (beehives/honey) and several non-food uses, including ornamentals (outdoor and container-grown, greenhouse, interior plantscapes, dip for cuttings), building surfaces/perimeters, ant mounds and certain crops (carrots and brassica/cole crops) grown for seed. It is registered for use on residential outdoor sites such as ornamental plants, ground cover, and shrubs. Tau-fluvalinate was first registered in one of its earlier forms, racemic fluvalinate, in 1983. Tau-fluvalinate was the subject of a Reregistration Eligibility Decision (RED), which was completed on September 28, 2005.

Anticipated Risk Assessment and Data Needs:

The Agency intends to require data needed to update and revise the ecological risk assessment for tau-fluvalinate (including an endangered species risk assessment). The Agency also intends to require data needed to update and revise the human health risk assessment. Below is a summary of the issues relevant to the registration review of tau-fluvalinate and the data the Agency plans to require.

Ecological Risk:

- The most recent ecological risk assessment was completed in 2005 to support the tau-fluvalinate RED.

- The Agency has not conducted a risk assessment that supports a complete endangered species determination. The ecological risk assessment planned during registration review will allow the Agency to determine whether use of tau-fluvalinate has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Services (the Services), as appropriate.

- An updated ecological assessment is planned to be conducted to incorporate new data and any relevant changes to risk assessment methodologies.

- The Agency intends to require the following data in order to conduct a complete ecological risk assessment, including an endangered species assessment, for all uses:

    - Guideline (GLN) 850.4100 – Seedling emergence Tier II[1]
    - GLN 850.4150 – Vegetative vigor, Tier II[1]
    - GLN 850.4400 – Aquatic plant growth (vascular plant toxicity), Tier II[1]
    - GLN 850.5400 – Aquatic plant growth (algal plant toxicity), Tier II[1]
    - GLN 835.4300 – Aerobic aquatic metabolism
    - GLN 834.4400 – Anaerobic aquatic metabolism
    - GLN 835.6100 – Terrestrial field dissipation
    - GLN 850.1025 – Acute toxicity to estuarine/marine invertebrate for the oyster
    - GLN 850.1350 – Aquatic invertebrate life-cycle for mysid shrimp
    - GLN 850.2100 – Avian oral toxicity test for passerine species

[1] The Agency anticipates requiring a Tier II study. A Tier I study may be conducted in lieu of a Tier II study with the understanding that adverse effects (even if <25%) would necessitate a Tier II study as well. The purpose of a Tier II study is to establish either a No Observed Adverse Effect Concentration (NOAEC) or a concentration at which there is a 5% observed effect (EC05) to be used in an endangered species risk assessment for nontarget plants. If neither an NOAEC nor an EC05 value is available, then the Agency may have to presume that tau-fluvalinate "may affect" listed nontarget plant species in the registration review endangered species risk assessment.

- Non-guideline – Test for Measuring the Effects of Sediment Associated Contaminants on Survival, Growth, and Reproduction on *Hyalella azteca* in USEPA 2000 Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates (EPA 600/R-99/064).
- Non-guideline – Life-cycle Test for Measuring the Effects of Sediment-associated Contaminants on *Chironomus dilutus or C. tentans* in USEPA 2000 Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates (EPA 600/R-99/064).
- Non-guideline – *Leptocheirus plumulosus* in USEPA 2001 Method for Assessing the Chronic Toxicity of Marine and Estuarine Sediment-associated Contaminants with the Amphipod *Leptocheirus plumulosus* (EPA 600/R-01/020).

- Please refer to the *Registration Review: Preliminary Problem Formulation for Environmental Fate, Ecological Risk, and Endangered Species Assessments for Tau-fluvalinate* located in the docket, for a detailed discussion of the anticipated risk assessment needs.

Human Health Risk:

- The most recent comprehensive human health assessment was completed in September 2005 in support of the tau-fluvalinate RED. Subsequent to the last risk assessment, the Agency has identified age-dependent pharmacokinetic factors associated with all pyrethroid insecticides that may lead to uncertainty regarding effects in children.

- Tau-fluvalinate residential use was restricted to commercial applicators in 2005. Therefore, a residential handler (homeowner) assessment was not conducted. However, since the 2005 assessment, two new homeowner end-use products have been registered for use on outdoor residential areas. During registration review, the Agency plans to assess potential residential handler exposure. A post-application exposure assessment of the current residential uses of tau-fluvalinate is not necessary as it is the Agency's standard practice not to assess post-application residential exposures from treated ornamentals or from perimeter, spot, and crack and crevice treatments to patios and other outside surfaces.

- During registration review, a new drinking water assessment will likely be conducted to take into account any new, relevant data submitted to the Agency or published in the literature. Input parameters to the drinking water model will also be updated to reflect current input parameter guidance.

- During registration review, the Agency foresees conducting a full reassessment of dietary (food and water), occupational, residential, and aggregate risk, taking into account any changes to toxicological endpoints, safety factors, exposure values, and applicable standard operating procedures.

- The Agency is in the process of examining its policies and processes regarding inhalation risk assessment and anticipates evaluating the need for a bystander inhalation risk assessment for tau-fluvalinate residential use during registration review.

- The developmental neurotoxicity study (DNT) was previously not requested for tau-fluvalinate. However, the Agency has new information regarding the potential for increased susceptibility in juveniles from pyrethroid exposures, and therefore, the DNT study is currently required for all pyrethroids, including tau-fluvalinate. Despite the existing DNT requirement, the Agency has determined that conducting additional DNT studies on any pyrethroids is not likely to contribute new information relevant for risk assessment. EPA believes the existing DNTs on six pyrethroids (bifenthrin, cyfluthrin, cyhalothrin, cypermethrin, fenpropathrin and deltamethrin) provide sufficient information to determine that the conclusions drawn from the DNTs, as combined, are applicable to all pyrethroids. Thus, EPA is hopeful that the registrants with DNT requirements will elect to cite the existing database to satisfy the DNT requirement rather than devoting new substantial resources associated with performing and evaluating new DNT studies. Detailed considerations supporting this conclusion can be found in "*Pyrethroids: Evaluation of Data from DNTs & Consideration of Comparative Sensitivity"*, available at http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.

- The Agency intends to require the following data in the registration review DCI for tau-fluvalinate in order to conduct a complete human health assessment:

    - GLN 870.7800 – Immunotoxicity
    - GLN 870.1300 – Acute inhalation
    - GLN 870.3465 – 90-day inhalation toxicity[2]
    - GLN 870.6200 – Acute neurotoxicity
    - GLN 870.6300 – Developmental neurotoxicity
    - GLN 870.3250 – 90-day dermal toxicity

- The Agency will make a decision regarding the need for an FQPA or other database uncertainty/safety factors for tau-fluvalinate following receipt of required toxicity data and following a final determination of the potential for increased susceptibility of infants and children to pyrethroid pesticides based on the results of all available data.

- Tau-fluvalinate is a member of the pyrethroid class of insecticides. This class also includes permethrin, cypermethrin, cyfluthrin, tau-fluvalinate, bifenthrin, fenpropathrin, and lambda-cyhalothrin, among others. EPA developed a draft science policy document

[2] While the inhalation guideline calls for a 90-day study duration, a 28-day study duration will satisfy the Agency's inhalation exposure data needs, and this will be noted in the data call-in that the Agency intends to issue.

on the proposed common mechanism of toxicity for naturally-occurring pyrethrins and synthetic pyrethroids (Proposed common mechanism grouping for the pyrethrins and pyrethroids, draft, May 19, 2009; http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064809a62df). This document was supported by the FIFRA Scientific Advisory Panel (SAP) and is available in the docket (http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a1f8d7). EPA will finalize the policy document on the pyrethroid common mechanism of toxicity taking into account the SAP comments. Pesticides with a common mechanism of toxicity are subject to cumulative risk assessment under the FQPA. Research is on-going by EPA's Office of Research and Development (ORD) to make improvements to the Stochastic Human Exposure and Dose Simulation (SHEDS) probabilistic exposure model, which are important for the cumulative risk assessment. EPA ORD is also developing physiologically-based pharmacokinetic models for several pyrethroids. The status of both of these research modeling efforts was reviewed by the FIFRA SAP in July, 2010 and meeting materials are available in the docket (http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2010-0378). For information regarding EPA's efforts to evaluate the risk to pyrethroids, see http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.

- Please refer to *Tau-fluvalinate. Human Health Assessment Scoping Document in Support of Registration Review,* located in the docket, for a detailed discussion of the anticipated risk assessment needs for human health.

Endocrine Disruptor Screening Program

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients (ais) and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application

agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Tau-fluvalinate is not among the group of 58 pesticide ais on the initial list to be screened under the EDSP. Under FFDCA sec. 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP orders/data call-ins for all registration review cases, including those for which EPA has already opened a registration review docket for a pesticide ai.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

Timeline:

EPA has created the following estimated timeline for the completion of tau-fluvalinate registration review.

Registration Review for Tau-fluvalinate – Projected Registration Review Timeline	
Activities	**Estimated Date**
Opening the Docket	
Open Docket and Public Comment Period	2010 – December
Close Public Comment	2011 – February
Case Development	
Final Work Plan	2011 – May
Issue DCI	2012 – Jan. – March
Data Submission[1]	2016 – Jan. – March
Open Public Comment Period for Draft Risk Assessments	2017 – July – Sept.
Close Public Comment Period	2017 – Oct. – Dec.
Registration Review Decision	
Open Public Comment Period for Proposed Registration Review Decision[2]	2018 – Jan. – March
Close Public Comment Period	2018 – April – June
Registration Review Decision and Begin Post-Decision Follow-up	2018
Total (years)	8

1. If the registrants choose to cite the 6 previously submitted DNT studies as explained above, then this time estimate will likely be shortened by approximately 2 years.
2. An assessment of the potential cumulative risk from the pyrethroid class of insecticides may impact this time estimate.

Guidance for Commenters:

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will carefully consider all comments as well as any additional

information or data provided in a timely manner prior to issuing a final work plan (FWP) for tau-fluvalinate.

Trade Irritants:

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Water Quality:

Tau-fluvalinate is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885. However, the pyrethroids as a group have been identified as a cause for impairment for three water bodies in Central Valley, CA: Del Puerto Creek, Ingram Creek Site (confluence with Hospital Creek to Hwy 33 crossing) and second Ingram Creek Site (confluence with San Joaquin River to confluence with Hospital Creek).

Nonetheless, no Total Maximum Daily Loads (TMDL) have been developed for tau-fluvalinate, based on information provided at http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES. More information on impaired water bodies and TMDLs can be found at http://www.epa.gov/owow/tmdl/. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process* (see: http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm) in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Environmental Justice:

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to tau-fluvalinate, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

Other Information:

Stakeholders are also specifically asked to provide information and data that will assist the Agency in refining the risk assessments, including any species-specific ecological effects determinations. The Agency is interested in receiving the following information:

1. confirmation on the following label information
    a. sites of application
    b. formulations
    c. application methods and equipment
    d. maximum application rates in units related to mass per unit area of treatment zone
    e. frequency of application, application intervals and maximum number of applications per season
    f. geographic limitations on use
2. use or potential use distribution use history
3. application timing (date of first application and application intervals)
4. typical interval (days)
5. state or local use restrictions
6. ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency
7. monitoring data, including existing or ongoing Publically Owned Treatment Works effluent monitoring data for the pyrethroids.

Next Steps:

After the 60-day comment period closes, the Agency will review and respond to any comments received in a timely manner, and then issue a FWP for tau-fluvalinate.

II. FACT SHEET

- Pesticide Chemical (PC) code: 109302
- Chemical Abstract Service (CAS) number: 102851-06-9
- Registration review case number: 2295
- Technical registrant: Wellmark International
- First registered for use in the U.S. in 1983.
- The RED for tau-fluvalinate was completed on September 28, 2005.
- There are currently 4 end-use products and 1 technical product registered.
- There are two Special Local Need (SLN) registrations for California for use on carrots, brassica vegetables, and cole crops (non-food uses; crops are grown for seed).
- Impregnated plastic strips used to treat varroa mites in beehives is the only food use, and the only tolerance is for tau-fluvalinate residues in honey.
- Pesticide Re-evaluation Division Chemical Review Manager: Molly Clayton, *clayton.molly@epa.gov*

- Registration Division Contact: Richard Gebken, *gebken.richard@epa.gov*

Use & Usage Information: (For additional details, please refer to the Appendix A and SLUA documents in the tau-fluvalinate docket.)

- Tau-fluvalinate is a broad-spectrum insecticide/miticide in the pyrethroid class of pesticides used to control a variety of post-emergent insects. It is registered for a single food use (beehives/honey) and several non-food uses, including commercial and residential ornamentals (outdoor and container-grown, greenhouse, interior plantscapes, dip for cuttings), building surfaces/perimeters, ant mounds and certain crops (carrots and brassica/cole crops) grown for seed.

- Formulation types include: ready-to-use liquids, flowable concentrate, and impregnated strips (bee hives).

- Tau-fluvalinate application methods include aerial (in California for the SLN), dipping, spray, fogger outdoor perimeter treatments, and impregnated plastic strips. Spoon or mound drench methods are used for ant mound treatments.

- The maximum concentration in residential outdoor use products is 0.61% ai. Tau-fluvalinate is labeled for use on greenhouse (non-food) plants, outdoor and interior ornamentals, Eugenia and pepper trees, and mound drenches at 0.34 lb ai/A. It is labeled for use on brassica/cole and carrot crops grown for seed in California at 0.15 lb ai/A; on flower and foliage cuttings at 5.0 fl oz ai/100 gal (as a dip); and on building perimeters at 3 tsp ai/5 gal/1000 sq ft. Use in beehives is labeled as one strip for each, of five combs or less in each bee chamber.

- Based on the 2010 SLUA, less than 500 pounds of tau-fluvalinate ai is used per year for agricultural proposes. It is primarily used on carrots grown for seed in California. The extent of current non-agricultural uses is unknown.

Recent and Pending Actions:

- The tau-fluvalinate labels have been amended to incorporate mitigation measures specified in the 2005 RED.

- In November, 2006 two new end-use products (EPA registration numbers 72155-71 and 72155-73) were registered for outdoor residential (homeowner) use, on sites such as flowers, ground covers, ornamentals, and shrubs.

Ecological Risk Assessment Status:

The following are key findings of the most recent ecological risk assessments for tau-fluvalinate. Please refer to the *Registration Review: Preliminary Problem Formulation for Ecological Risk,*

Environmental Fate, Endangered Species, and Drinking Water Assessment for Tau-fluvalinate, located in the docket, for a detailed discussion of previous ecological risk assessments.

- The most recent ecological assessment, completed in July 2005, identified potential acute and chronic risks to aquatic organisms and mammals. There was also a concern for non-target terrestrial invertebrates.

- In 2005, there were significant ecological data gaps, which limited the Agency's ability to assess acute risk to aquatic organisms, aquatic plants, and terrestrial plants and chronic risk to marine/estuarine invertebrates. The risk assessment did not indicate a concern for birds, based on data available at the time

- The use pattern for tau-fluvalinate suggested that the potential risks would likely be limited to those geographic areas where the chemical is most widely used, including use on ornamentals in California, Oregon, Michigan, Florida, Pennsylvania, and Texas.

Human Health Risk Assessment Status:

The following are key findings of the most recent human health risk assessments for tau-fluvalinate. Please refer to *Tau-fluvalinate: Human Health Assessment Scoping Document in Support of Registration Review*, located in the docket, for a detailed discussion of previous human health risk assessments.

- The most recent comprehensive human health risk assessment was completed September 2005 in support of reregistration.

Hazard Characterization:

- Tau-fluvalinate, like other pyrethroid insecticides, causes neurotoxicity in insects and mammals by the modulation of nerve axon sodium channels. Pyrethroids interfere with the ability of the nervous system to relay nerve transmissions resulting in effects such as tremors, excessive grooming, and salivation. Similar signs of neurotoxicity were observed in the guideline studies conducted with tau-fluvalinate.

- Data indicate no evidence of carcinogenicity in mice or rats, and there is no concern for mutagenicity.

- At the time of reregistration, A 100X uncertainty factor was used to account for interspecies extrapolation and intraspecies variability (10X and 10X, respectively). Based on a review of both hazard and exposure data, the Agency reduced the special FQPA safety factor to 1X.

Dietary (Food and Drinking Water):

- In 2005, exposure from drinking water was incorporated in the acute and chronic risk assessments using the 1-in-10 year annual peak and average concentrations of surface water, respectively. Nearly all the estimated dietary exposure to tau-fluvalinate was from drinking water.

- The acute and chronic dietary (food + drinking water) risk estimates were below the Agency's level-of-concern for the general population and all population subgroups.

Residential:

- In 2005, since there were no registered homeowner uses, a residential handler risk assessment was not performed. The commercial applications to residential settings were limited to spot treatments or building perimeters, resulting in minimal potential post-application exposure. In accordance with the Agency's standard residential assessment practices, post-application risk was not assessed.

Aggregate:

- The 2005 aggregate risk assessment considered only combined food and drinking water exposures. The aggregate risk estimates were below the Agency's level-of-concern.

Occupational:

- The 2005 occupational risk assessment considered inhalation exposure only; risk from potential occupational dermal exposures was not assessed quantitatively. No toxicity endpoint was selected for dermal exposure in available toxicology studies, and dermal exposures to products containing tau-fluvalinate were expected to be largely self-limiting due to the irritation that occurs as a result of the "pyrethroid reaction", characterized by tingling sensations and/or itching, often severe, upon contact with the chemical. Potential dermal risk was addressed by labeling instructing the user to avoid contact with skin and instructions to wash the affected area immediately following contact.

- At the time of the RED, the Agency did not have data with which to estimate possible tau-fluvalinate exposures from the greenhouse fogger use. To address this area of uncertainty, the Agency required an occupational post-application exposure study for greenhouse exposure scenarios (OPPTS Guideline 875.2500). These data were submitted and confirmed that the 12-hour restricted entry interval specified in the 2005 was adequately protective of post-application greenhouse inhalation risk.

- All occupational handler and post-application inhalation risk estimates were below the Agency's level-of-concern.

Cumulative:

- Tau-fluvalinate is a member of the pyrethroid class of insecticides. This class also includes permethrin, cypermethrin, cyfluthrin, tau-fluvalinate, bifenthrin, fenpropathrin, and lambda-cyhalothrin, among others. EPA developed a draft science policy document on the proposed common mechanism of toxicity for naturally-occurring pyrethrins and synthetic pyrethroids (Proposed common mechanism grouping for the pyrethrins and pyrethroids, draft, May 19, 2009; http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064809a62df). This document was supported by the FIFRA Scientific Advisory Panel (SAP) and is available in the docket (http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a1f8d7). EPA will finalize the policy document on the pyrethroid common mechanism of toxicity taking into account the SAP comments. Pesticides with a common mechanism of toxicity are subject to cumulative risk assessment under the FQPA. Research is on-going by EPA's Office of Research and Development (ORD) to make improvements to the Stochastic Human Exposure and Dose Simulation (SHEDS) probabilistic exposure model, which are important for the cumulative risk assessment. EPA ORD is also developing physiologically-based pharmacokinetic models for several pyrethroids. The status of both of these research modeling efforts was reviewed by the FIFRA SAP in July, 2010 and meeting materials are available in the docket (http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2010-0378). For information regarding EPA's efforts to evaluate the risk to pyrethroids, see http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.

Incidents:

Ecological:

- The Agency consulted the Ecological Incident Information System database for reports of ecological incidents, and no incidences have been reported for tau-fluvalinate.

Human Health:

- The OPP Incident Data System (IDS) and the Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR) databases were consulted for pesticide incident data on the active ingredient tau-fluvalinate.

    - For IDS, from 2000 to May 25, 2010 there are 90 cases reported for tau-fluvalinate of minor, unknown, or no effects. For these minor incidents, there are no individual reports available that would provide details about the incidents, and single chemical incidents are not distinguished from multiple chemical incidents. There was one case reported for tau-fluvalinate in the database with moderate severity. In this case, an unknown age female reported dermal effects.

- For NIOSH SENSOR from 1998 to 2007, seven cases of low to moderate severity were reported that involved the active ingredient tau-fluvalinate. The health effects reported included: gastrointestinal, respiratory, ocular, neurological, and dermal.

Tolerances and International Harmonization:

The only U.S. tolerance is established for tau-fluvalinate residues in honey. Currently, Codex, Canada, and Mexico do not have MRLs established for the use of tau-fluvalinate. The Agency will work to harmonize tolerances/MRLs during registration review as appropriate.

DCIs:

A generic DCI (GDCI-109302-26155) was issued for tau-fluvalinate in March 2007. All data requirements identified in the DCI have been fulfilled.

Labels:

Active Section 3 registrations can be obtained from the Pesticide Product Label System (PPLS) website at http://oaspub.epa.gov/pestlabl/ppls.home.

III. Summary of Data Gaps – Tau-fluvalinate

The table below summarizes all anticipated data needs for tau-fluvalinate.

Guideline Number	Anticipated Data Requirement	Test Material	Estimated Timeframe
850.4100	Seedling emergence Tier II[1]	TGAI	12
850.4150	Vegetative vigor, Tier II[1]	TGAI	12
850.4400	Aquatic plant growth (vascular plant toxicity), Tier II[1]	TGAI	12
850.5400	Aquatic plant growth (algal plant toxicity), Tier II[1]	TGAI	12
835.4300	Aerobic aquatic metabolism	TGAI	24
835.4400	Anaerobic aquatic metabolism	TGAI	24
835.6100	Terrestrial field dissipation	TGAI	24
850.1500	Fish full life cycle for one freshwater species	TGAI	24
850.1400	Fish early-life stage toxicity test for one freshwater species	TGAI	12
850.1350	Aquatic invertebrate life-cycle for mysid shrimp	TGAI	12
850.2100	Avian oral toxicity test for passerine species	TGAI	12
850.1025	Acute toxicity to estuarine/marine invertebrate for the oyster	TGAI	12
Non-guideline	Test for Measuring the Effects of Sediment Associated Contaminants on Survival, Growth, and Reproduction on	TGAI	24

Guideline Number	Anticipated Data Requirement	Test Material	Estimated Timeframe
	Hyalella azteca in USEPA 2000 Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates. EPA 600/R-99/064		
Non-guideline	Life-cycle Test for Measuring the Effects of Sediment-associated Contaminants on *Chironomus dilutus or C. tentans* in USEPA 2000 Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates. EPA 600/R-99/064	TGAI	24
Non-guideline	*Leptocheirus plumulosus* in USEPA 2001 Method for Assessing the Chronic Toxicity of Marine and Estuarine Sediment-associated Contaminants with the Amphipod *Leptocheirus plumulosus.* EPA 600/R-01/020	TGAI	24
870.7800	Immunotoxicity	TGAI	12
870.1300	Acute inhalation toxicity study	TGAI	8
870.3465	90-day inhalation toxicity study[2]	TGAI	24
870.6200	Acute neurotoxicity	TGAI	24
870.6300	Developmental neurotoxicity[3]	TGAI	48
870.3250	90-day dermal toxicity study	TGAI	24

[1]The Agency anticipates requiring a Tier II study. A Tier I study may be conducted in lieu of a Tier II study with the understanding that adverse effects (even if <25%) would necessitate a Tier II study as well. The purpose of a Tier II study is to establish either a No Observed Adverse Effect Concentration (NOAEC) or a concentration at which there is a 5% observed effect (EC05) to be used in an endangered species risk assessment for nontarget plants. If neither an NOAEC nor an EC05 value is available, then the Agency may have to presume that tau-fluvalinate "may affect" listed nontarget plant species in the registration review endangered species risk assessment.

[2]While the inhalation guideline calls for a 90-day study duration, a 28-day study duration will satisfy the Agency's inhalation exposure data needs, and this will be noted in the data call-in that the Agency intends to issue.

[3]EPA believes the existing DNTs on six pyrethroids (bifenthrin, cyfluthrin, cyhalothrin, cypermethrin, fenpropathrin and deltamethrin) provide sufficient information to determine that the conclusions drawn from the DNTs, as combined, are applicable to all pyrethroids. Thus, EPA is hopeful that the registrant will cite the existing database to satisfy the DNT requirement rather than devoting new substantial resources to performing and evaluating a new DNT study for tau-fluvalinate.